

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5149. Testosterone, desoxycorticosterone acetate, and progesterone. (F. D. C. No. 38566. S. Nos. 3-583 M, 8-859 M, 8-871 M.)

INFORMATION FILED: 5-21-56, S. Dist. Calif., against Coast Chemical Co., a corporation, and Cleo O. Bedwell, president.

SHIPPED: Between 11-9-54 and 2-1-55, from California to Arizona and Massachusetts.

LABEL IN PART: (Btl.) "10 cc Sterile Multiple Dose Vial Testosterone Crystalline U. S. P. In Aqueous Macrosuspension 50 Mgs. per cc Preservative: Merthiolate—1:20 M For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription. Made especially for Star Pharmacy, Wholesale Division Boston & Cambridge 39, Mass.," "10 cc Sterile Desoxycorticosterone Acetate U. S. P. Aqueous Macrosuspension of Desoxycorticosterone Acetate 5 mgs. per cc When Properly Shaken Purified Crystalline Adrenal Cortical Hormone preparation. Coast Pharmaceuticals Division of Coast Chemical Co. Los Angeles California," "Lot No. 5997 Caution: Federal law prohibits dispensing without prescription. For Intramuscular Injection Only," and "10 cc Sterile Progesterone U. S. P. In Aqueous Macrosuspension When properly shaken, each cc contains: Progesterone 50 mgs. (50 I. U.) Preservative: Merthiolate—1:20 M For Intramuscular Use Only Distributed by Rocky Mountain Pharmacal Co. Phoenix, Arizona * * * Caution: Federal law prohibits dispensing without prescription."

CHARGE: 501 (c)—when shipped, the purity and quality of the *testosterone* and *desoxycorticosterone acetate* fell below that which they were represented to possess in that these articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms; and 502 (a)—the word "Sterile" in the labeling of the *progesterone* was false and misleading since the article was not sterile but was contaminated with viable micro-organisms.

PLEA: Nolo contendere.

DISPOSITION: 8-1-56. Corporation fined \$450 and individual \$225. Corporation also placed on probation for 1 year.

5150. Dexatal tablets (Gracital). (F. D. C. No. 39243. S. No. 22-883 M.)

QUANTITY: 400 100-tablet btls. at Meriden, Conn.

SHIPPED: 10-6-55, from Worcester, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "Product No. 10 Graco Gracital Dextro Amphetamine Sulfate and Amobarbital C. T. Caution: Federal law prohibits dispensing without prescription * * * Each tablet contains: Dextro Amphetamine Sulfate, 5 mg. * * * Note: New Product Name Gracital Formerly Called Dexatal."

RESULTS OF INVESTIGATION: Examination showed that the article contained no significant amount of dextro-amphetamine sulfate.

LIBELED: 5-23-56, Dist. Conn.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 5 mg. of dextro-amphetamine sulfate; and

*See also No. 5141.